Betsy Codrea
Regulatory Product Manager
Gowan Company
P.O. Box 5569
Yuma, AZ 85366-5569

Dear Ms. Codrea:

Your company has submitted, or has indicated an intention to submit, a probabilistic dietary (Monte Carlo) risk assessment to EPA in support of the reregistration of Oxydemeton-Methyl. In addition to any information requested previously, we need the following information to permit verification of the probabilistic dietary risk assessment:

1. Disclosure of the consumption database used in the assessment. By the database, we mean a detailed listing of the consumption data as used in the assessment so that EPA can independently evaluate the assumptions used in deriving the estimates of consumption. At a minimum this must include (a) identification of the consumption survey used and a submission of all survey data if those survey data have not previously been revised by EPA; (b) a list of all individual food items (e.g., pizza, apple pie) used in the assessment (these items are often referred to by "food codes"); and (c) the mapping that translates the individual food items into the commodities on which tolerances are established. The submission must provide all food codes associated with each of the commodities that currently have a tolerance for the pesticide and, if applicable, each commodity or commodities for which a tolerance is being sought.

2. The assumptions and algorithms used in performing the assessment must be defined and explained. These include: sampling procedures for consumption data and other datasets; any modeling of datasets; extrapolation procedures beyond the range of the dataset; conventions used in incorporating market share data and/or percent crop treated data, or in using descriptive statistics in lieu of individual data values.

3. RDF (Residue Data Files) must be provided in electronic format. Generally, these consist of all the crop field trial data points that represent the maximum labeled rate and the minimum labeled PHI for each crop, as well as PDP monitoring data for blended commodities only. It is important to note that the RDFs must contain **all crops currently registered, even if you intend to drop some of the uses**. You should not eliminate any data points even if you believe them to be outliers. If you intend to drop crops or believe certain data points to be outliers, you are welcome to note that in your submission and we will take these factors into consideration.

   Preference will be given to data from field trials conducted at maximum label rate and minimum PHI. However, on a case-by-case basis, data from field trials conducted at plus or minus 25% of the labeled maximum rate, and plus or minus 25% of the minimum labeled PHI, may be used provided no appreciable bias is introduced in the residue values obtained.

4. Certification that all field trial data resulting from the maximum labeled rate and minimum labeled PHI application scenarios are included in the RDF must be provided. Include the MRID # (Master Record Identification Numbers) associated with each study from which data points have been used.

Finally, it should be noted that your assessment must reflect the toxicity endpoint (NOAEL) identified by EPA's Hazard Identification Committee for use in acute dietary assessments. If you believe that another endpoint is appropriate, you may present the rationale for its consideration in your submission.

Sufficient information must be provided to permit the assessment to be reproduced and the rationale and assumptions behind the assessment to be clear and transparent. This information is necessary to meet EPA's recently-issued guidance on the use of Monte Carlo risk assessments. Guiding Principles for Monte Carlo Analysis (March 1997). That policy states that:

> The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results are to be document and easily located in the report . . . . Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.

This supporting information should be submitted at the same time as your revised Monte Carlo submissions. RDF files should be submitted on a diskette along with a hard copy. One

complete set of information (including the RDF diskette) should be provided directly to the Chemical Review Manager for ODM, Kathleen Meier. A duplicate package should be submitted through the normal Document Processing channels. The duplicate package should include one RDF diskette and three (3) paper copies of all files and material being submitted. If your original Monte Carlo submission was assigned an MRID #, that number should be referenced in this submission of supporting documentation.

Until the Agency receives this supporting information, we will not be able to complete review of your Monte Carlo submission or rely on it for decision making.

If you have any questions or comments, please contact Kathleen Meier (703)308-8017.

Sincerely yours,

Jack Housenger, Acting Director
Special Review and
Reregistration Division